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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional): 10177-142-999

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on _____

Signature _____

Typed or printed name _____

Application Number	Filed
09/891,715	June 26, 2001

First Named Inventor: Mueller et al.

Art Unit	Examiner
3763	Rodriguez, Cris Lorien

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

- ☐ applicant/inventor.
- ☐ assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)
- ☒ attorney or agent of record. Registration number 54,390
- ☐ attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____

Signature

Brent P. Ray
Typed or printed name

212-326-8358
Telephone number

August 16, 2006
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☒ *Total of 1 forms are submitted.

Express Mail No. EV475142989US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No. 10177-142-999
CAM: 008563-999140

Group Art Unit:	3763	
Examiner:	Rodriguez, Cris Lorien	
Inventor:	Mueller et al.	
Serial No.:	09/891,715	**PRE-APPEAL BRIEF CONFERENCE REQUEST**
Filed:	June 26, 2001	
For:	METHOD AND APPARATUS FOR TREATING ISCHEMIC TISSUE	

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicants hereby request review of the Final Rejection mailed February 17, 2006 ("Final Rejection") of the above-captioned application prior to filing an appeal brief for the reasons set forth below. Applicants submit that the Final Rejection fails to establish a *prima facie* rejection.

I. PROSECUTION SUMMARY

Claims 35-47 stand rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 6,264,650 to Hovda et al. ("Hovda"). Independent claims 35 and 47 recite devices for treating tissue comprising, in part, "at least one therapeutic substance delivery effector located at the distal end of the elongate shaft, capable of delivering a therapeutic substance."

Therapeutic substances treat or cure diseases or disorders, or provide some other remedial function.

Hovda describes a device for electrosurgical treatment of an intervertebral disc. The device has a plurality of electrodes capable of applying electrical energy to a target location to ablate or stiffen tissue. In some embodiments, "[t]he current flow path between the electrode terminals and the return electrode(s) may be generated by submerging the tissue site in an electrical conductive fluid...or by directing an electrically conducting fluid along a fluid path to the target site (i.e., a liquid, such as isotonic saline, hypotonic saline or a gas, such as argon)." (Hovda at 15:62-16:1). Other conductive fluids, such as "blood or intracellular saline" are also described. (*Id.* at 16:10-12).

The Examiner first relied upon Hovda as an anticipatory reference in the August 4, 2005 Non-Final Office Action to reject then-pending claims 35-46. In their Amendment under 37 C.F.R. § 1.111 dated December 5, 2005, Applicants added claim 47, and argued that Hovda did not describe a "therapeutic substance delivery effector." In the Final Rejection, the Examiner affirmed the rejection of claims 35-46 as anticipated by Hovda, and extended the same to claim 47. The Examiner also introduced the article "Use of Epidural Steroids in the Treatment of Sciatica," AMERICAN FAMILY PHYSICIAN, Vol. 56, No. 8 (1997) ("American Family Physician article") as purporting to show that the isotonic saline on Hovda is a therapeutic substance. Applicants thereafter held a telephonic interview with the Examiner on April 4, 2006, disputing the Examiner's statement regarding the American Family Physician article, noting that isotonic saline was used in the described study as a placebo. The Examiner disagreed, as memorialized in the her Interview Summary dated April 10, 2006. Thereafter, Applicants filed an Amendment under C.F.R. § 1.116 dated May 12, 2006, further disputing the Examiner's characterization of the American Family Physician article, and citing two other articles contradicting the Examiner's statements regarding isotonic saline. The Examiner again maintained the rejections in her Advisory Action dated June 7,

2006, and cited another article purporting to describe a therapeutic effect of isotonic saline: "Epidural Corticosteroid Injections for Sciatica due to Herniated Nucleus Pulposus," THE NEW ENGLAND JOURNAL OF MEDICINE, Vol. 336, No. 23 (June 5, 1997) ("NE Journal article").

II. FAILURE TO ESTABLISH A *PRIMA FACIE* CASE OF ANTICIPATION

A *prima facie* case of anticipation has not been made with regard to independent claims 35 and 47, and their dependent claims, because Hovda fails to disclose each and every element of claims 35 and 47.

Hovda does not describe a "therapeutic substance delivery effector" for deliverying a therapeutic substance. Hovda does disclose the introduction of a conductive fluid to generate a current flow path between electrical terminals, but does not describe the conductive fluid as being a therapeutic substance. In fact, Hovda clearly indicates that the conductive fluid is an *optional* practice (*id.* at 15:62-16:1), and when used, Hovda discloses a "suction tube 211 for aspirating the fluid after it has completed the conductive path" (*see id.* at 26:27-32). Aspiration is indicated as helpful because it "*prevents the fluid from flowing into the body.*" (*Id.* at 26:19-20).[1] Thus, Hovda fails to disclose that its conductive fluid is a therapeutic substance and that its devices includes a therapeutic substance delivery effector.

The Examiner repeatedly argues that because Hovda discloses the use of isotonic saline as a conductive fluid, and because isotonic saline is purportedly therapeutic, that Hovda has a "therapeutic substance delivery effector." This argument is without merit. The American Family Physician article and the NE Journal article do not support the Examiner's assertion that isotonic saline is a therapeutic substance, and in fact, refute the Examiner's position. In both articles, isotonic saline is used as a *placebo* in a randomized, double-blind trial. By definition, a placebo is a substance that *lacks therapeutic effect*. Otherwise, there

[1] Emphasis added unless otherwise noted.

would be no reliable way to discern any therapeutic effects of the active test substance used in the study (in both articles, methylprednisolone). This alone contradicts the Examiner's unsupported statement in her Advisory Action that isotonic saline in the American Family Physician article "was used for therapeutic purposes."

Moreover, the Examiner stated in her Advisory Action that the NE Journal article "shows improvements with isotonic solutions in the herniated area." This argument also misses the mark. The NE Journal article study, using isotonic saline as a placebo, conducted three-week trials of injections, and concluded that epidural injections of methylprednisolone were only marginally helpful over the results obtained with a placebo. The NE Journal article makes no statements or implied remarks that the placebo was the *cause* of patient improvements, and instead concluded there was an "absence of a therapeutic effect of [the] epidural methylprednisolone injections." (*Id.* at 1639). The logical conclusion is that the patients in the study simply *improved over time*, regardless of what injections they received — not that the placebo had a therapeutic effect.

For at least the above reasons, Applicants submit that independent claims 35 and 47 are in condition for allowance. As claims 36-46 depend from independent claim 35, Applicants submit these claims are likewise in condition for allowance.

Respectfully submitted,

Date: August 16, 2006

54,390
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